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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,835	09/28/2006	Craig A. Coburn	21538YP	3654
MERCK AND	7590 05/23/200 CO., INC	EXAMINER		
PO BOX 2000		KOLKER, DANIEL E		
RAHWAY, NJ 07065-0907			ART UNIT	PAPER NUMBER
			1649	
			MAIL DATE	DELIVERY MODE
			05/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
Office Action Comments	10/594,835	COBURN ET AL.				
Office Action Summary	Examiner	Art Unit				
	DANIEL KOLKER	1649				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on 28 Se	entember 2006					
	action is non-final.					
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
·— · · ·	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
closed in accordance with the practice under Lx parte Quayle, 1933 C.D. 11, 433 C.D. 213.						
Disposition of Claims						
4) Claim(s) <u>1-23</u> is/are pending in the application.	I)⊠ Claim(s) <u>1-23</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdraw	4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
6) Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) <u>1-23</u> are subject to restriction and/or e	8) Claim(s) <u>1-23</u> are subject to restriction and/or election requirement.					
Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:						
<u> </u>	1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
Attachment(s)  1) \[ \sum \text{Notice of References Cited (PTO-892)} \] 4) \[ \sum \text{Interview Summary (PTO-413)} \]						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date						
3) Information Disclosure Statement(s) (PTO/SB/08)  5) Notice of Informal Patent Application						
Paper No(s)/Mail Date 6) U Other:						

Application/Control Number: 10/594,835 Page 2

Art Unit: 1649

## **DETAILED ACTION**

1. The preliminary amendment filed 28 September 2006 has been entered. Claims 1-23 are pending.

## Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1 - 18, drawn to processes for determining interaction of a substance with APP or  $A\beta$ .

Group 2, claim(s) 19 – 20, drawn to substances which interact with APP or A $\beta$ , of undisclosed structure.

Group 3, claim(s) 21 – 22, drawn to compounds of formula (I).

Group 4, claim(s) 23, drawn to a method of treating Alzheimer's disease.

3. The inventions listed as Groups 1-4 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the first claimed technical feature is a process for determining interaction between a test substance and A $\beta$  or APP, which requires test solutions comprising APP, a substance, and a first antibody. This technical feature is not present in any of the claims of groups 2-4. Group 2 is drawn to a compound which can be of any structure and which might be identified a screening assay, but the screening assay is neither necessary nor sufficient to make the product. Group 3 is drawn to a product of defined structure, which cannot be made by the screening assay. Group 4 is drawn to a method of treating a disease, which cannot be accomplished by following the steps of the group 1 claims. As the technical features of group 1 are not present in the claims of groups 2-4 and the

Art Unit: 1649

technical features of groups 2 – 4 are not present in the claims of group 1, unity of invention is lacking. Note that PCT Rule 13 does not allow for multiple products or methods in a single application.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

- 5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. <u>All</u> claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim

Application/Control Number: 10/594,835 Page 4

Art Unit: 1649

will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL KOLKER whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel E. Kolker, Ph.D./
Patent Examiner, Art Unit 1649
May 21, 2008